Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in June 2006.

New Approvals

ANADA Number: 200-424

Pioneer Product:	141-233
Trade Name:	Heifermax™/Optaflexx® / Rumensin® / Tylan®
Ingredients:	Melengestrol acetate, ractopamine hydrochloride, monensin sodium, tylosin phosphate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	April 27, 2006
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Cattle, heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles to make dry and liquid,four-way combination Type C medicated feeds.
Concentration:	Melengestrol acetate - 500 milligrams activity per pound of Type A Medicated Article. Ractopamine hydrochloride - 45 grams activity per pound of Type A Medicated Article. Monensin sodium - 20, 30, 45, 60, 80, or 90.7 grams activity per pound of Type A Medicated Article. Tylosin phosphate - 10, 40, or 100 grams activity per pound of Type A Medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces* (*Corynebacterium*) *pyogenes*, and suppression of estrus (heat) in heifers fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	*21CFR 556.380:* Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat. *21CFR 556.570:* Ractopamine: The tolerances for residues of ractopamine are established as follows: 0.03 part per million in muscle and 0.09 part per million in liver. *21CFR 556.420:* Monensin: A tolerance of 0.05 part per million is established for negligible residues in edible tissues. *21CFR 556.740:* Tylosin: Tolerances are established for residues of tylosin in edible products as follows: 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days

21CFR 558.500

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 121-042

Trade Name:	Anthelcide EQ® Paste
Ingredients:	Oxibendazole
Sponsor:	Pfizer, Inc.
Approval Date:	April 12, 2006

This application provides for revised food safety labeling.

21CFR 520.1638

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: 109-722

Trade Name: Anthelcide EQ® Suspension
Ingredients: Oxibendazole
Sponsor: Pfizer, Inc.
Approval Date: April 17, 2006

This application provides for revised food safety labeling.

21CFR 520.1640

NADA Number: 008-622

Trade Name: Terramycin-343
Ingredients: Oxytetracycline Hydrochloride
Sponsor: Pfizer, Inc
Approval Date: May 9, 2006

This application provides for revised labeling of oxytetracycline soluble powder with the current genus for the causative bacteria for American foul brood of honeybees.

21CFR 520.1660d

Suitability Petition Action

Number: 06P-0093/PRC1
Sponsor: ECO Animal Health
Petition: Request permission for reconsideration to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® 1%, Merial Ltd., NADA 128-409, by the following characteristic(s): The generic will differ in strength (2%) from the pioneer product (1%).
Action: Filed June 2, 2006.

Number: 06P-0263/CP1
Sponsor: Sparhawk Laboratories, Inc.
Petition: Request permission to file an ANADA for a generic new animal drug neomycin which differs from the pioneer product, Neomycin Soluble Powder, Pharmacia & Upjohn Co., NADA 011-315 by the following characteristics: The generic will differ in dosage form.
Action: Filed June 21, 2006.

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to correct the indications for use for the 200 milligram (mg)/milliliter (mL) strength of oxytetracycline injectable solution used in beef cattle for the treatment and control of various bacterial diseases. Certain indications of use for the 300 mg/mL strength of oxytetracycline injectable solution appear to have been included as an error in the section for the 200 mg/mL strength solution during reformatting (69 FR 31878, June 8, 2004). This action is being taken to improve the accuracy of the regulations. This rule is effective June 6, 2006.

For further information contact: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail:george.haibel@fda.hhs.gov.

The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of an original new animal drug application (NADA) that appeared in the Federal Register of April 27, 2006 (71 FR 24814). FDA is correcting a paragraph designation in the table for lasalocid cattle feeds which was drafted in error. This correction is being made to improve the accuracy of the animal drug regulations.

This rule is effective June 15, 2006.

Section 558.311 is corrected in the table in the ``Lasalocid sodium in grams per ton" column, in the entry for use of lasalocid at 30 to 600 grams per ton in combination with chlortetracycline at 500 to 4000 grams per ton, by removing the second paragraph designation ``(xxiii)" and by adding in its place the paragraph designation ``(xxviii)". For further information contact: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9019, e-mail: george.haibel@fda.hhs.gov.

The Food and Drug Administration (FDA) is correcting the animal drug regulations 21 CFR Part 558. New Animal Drugs For Use in Animal Feeds. In Title 21 of the Code of Federal Regulations, Parts 500 to 599, revised as of April 1, 2006, on page 391, in Sec. 558.76, paragraphs (a), (b), and (d)(1) have been corrected.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ``Q9 Quality Risk Management.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides principles and examples of tools for quality risk management that can be applied to all aspects of pharmaceutical quality throughout the lifecycle of drug substances, drug products, and biological and biotechnological products. The guidance is intended to enable regulators and industry to make more effective and consistent risk-based decisions.

Submit written or electronic comments on agency guidance at any time. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number [Docket No. 2005D-0288].

For further information contact: Regarding the guidance: H. Gregg Claycamp, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301-827-6505; Albinus D Sa, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9044; Anna M. Flynn, Center for Biologics Evaluation and Research (HFM-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6201; or Diana J. Kolaitis, Office of Regulatory Affairs (HFR-NE1), Food and Drug Administration, 158-15 Liberty Ave., Jamaica, NY 11433, 718-662-5612.
Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

The Food and Drug Administration (FDA) is announcing the withdrawal of five and the revision of two guidances for industry, because some of the principles in these guidances are inconsistent with the agency's initiative, Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century (CGMP Initiative). Several of the guidances listed in this notice are cross-Center guidances relating to products regulated by the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM).

[Docket Nos. 1985D-0243 (formerly 85D-0243), 1984D-0115 (formerly 84D-0115), 1998D-0362 (formerly 98D-0362), 2003D-0061 (formerly 03D-0061), 2006D-0198, 1998D-0994 (formerly 98D-0994), 2003D-0571, 2000D-0186 (formerly 00D-0186), 1993D-0139 (formerly 93D-0139), 1996D-0010 (formerly 96D-0010), 1996D-0028 (formerly 96D-0028), 2001D-0361 (formerly 01D-0361), 2002D-0237 (formerly 02D-0237), 2002D-0231 (formerly 02D-0231), 1997D-0448 (formerly 97D-0448), 1998D-0374 (formerly 98D-0374), 2000D-1418 (formerly 00D-1418), 2005D-0021].

For further information contact: For products regulated by CDER: Jon Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3550, Silver Spring, MD 20993-0002, 301-796-2020. For products regulated by CBER: Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration 1401 Rockville Pike, suite 200N Rockville, MD 20852-1448, 301-435-5681. For products regulated by CVM: Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., MPN II, Rockville, MD 20855, 301-827-6956.

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (177) entitled ``Specifications: Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products'' (VICH GL40). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document provides general principles through recommendations on the setting and justification, to the extent possible, of a uniform set of international specifications for biotechnological and biological products to support new marketing applications.

Submit written or electronic comments at any time. Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to

the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number [Docket No. 2005D-0200].

For further information contact: Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (176) entitled ``Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances'' (VICH GL-39). This guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to assist to the extent possible, in the establishment of a single set of recommended global specifications for new veterinary drug substances and medicinal products. It provides guidance through recommendations on the setting and justification of acceptance criteria and the selection of test procedures for new veterinary drug substances of synthetic chemical origin, and new medicinal products produced from them, which have not been registered previously in the United States, the European Union, or Japan.

Submit written or electronic comments at any time. Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number [Docket No. 2005D-0199].

For further information contact: Dennis Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry (137) entitled ``Analytical Methods Description for Type C Medicated Feeds.'' This draft guidance provides our recommendations for describing methods for analyzing new animal drugs in Type C medicated feeds.

Submit written or electronic comments on this draft guidance by September 11, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance and the docket number [Docket No. 2006D-0254]. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Copies of the draft guidance document entitled ``Analytical Methods Description for Type C Medicated Feeds'' may be obtained from the CVM Home Page (http://www.fda.gov/cvm) and from the Division of Dockets Management Web site http://www.fda.gov/ohrms/dockets/default.htm).

For further information contact: Rebecca L. Owen, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9842, e-mail: rebecca.owen@fda.hhs.gov.